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In Re: Patent Term Extension
Application for
U.S. Patent No. 6,051,698

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 6,051,698, which claims the human drug product Macugen® (pegaptanib sodium) and a method of manufacture for Macugen® (pegaptanib sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 944 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 944 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 20, 2006, (71 Fed. Reg. 54998). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase} \\ &= \frac{1}{2} (2,128 - 607) + 184 \\ &= 944 \text{ days (2.6 years)}\end{aligned}$$

Since the regulatory review period began August 21, 1998, before the patent issued (April 18, 2000), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 21, 1998, to and including April 18, 2000, is 607 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	6,051,698
Granted:	April 18, 2000
Original Expiration Date ¹ :	October 17, 2012
Applicant:	Nebojsa Janjic, et al.

¹Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record: Gilead Sciences, Inc.

Title: Vascular Endothelial Growth Factor (VEGF) Nuclei Acid Ligand Complexes

Product Trade Name: Macugen® (pegaptanib sodium)

Term Extended: 944 days

Expiration Date of Extension: May 19, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Ti
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: Macugen® (pegaptanib sodium)
FDA Docket No.: 2005E-0234